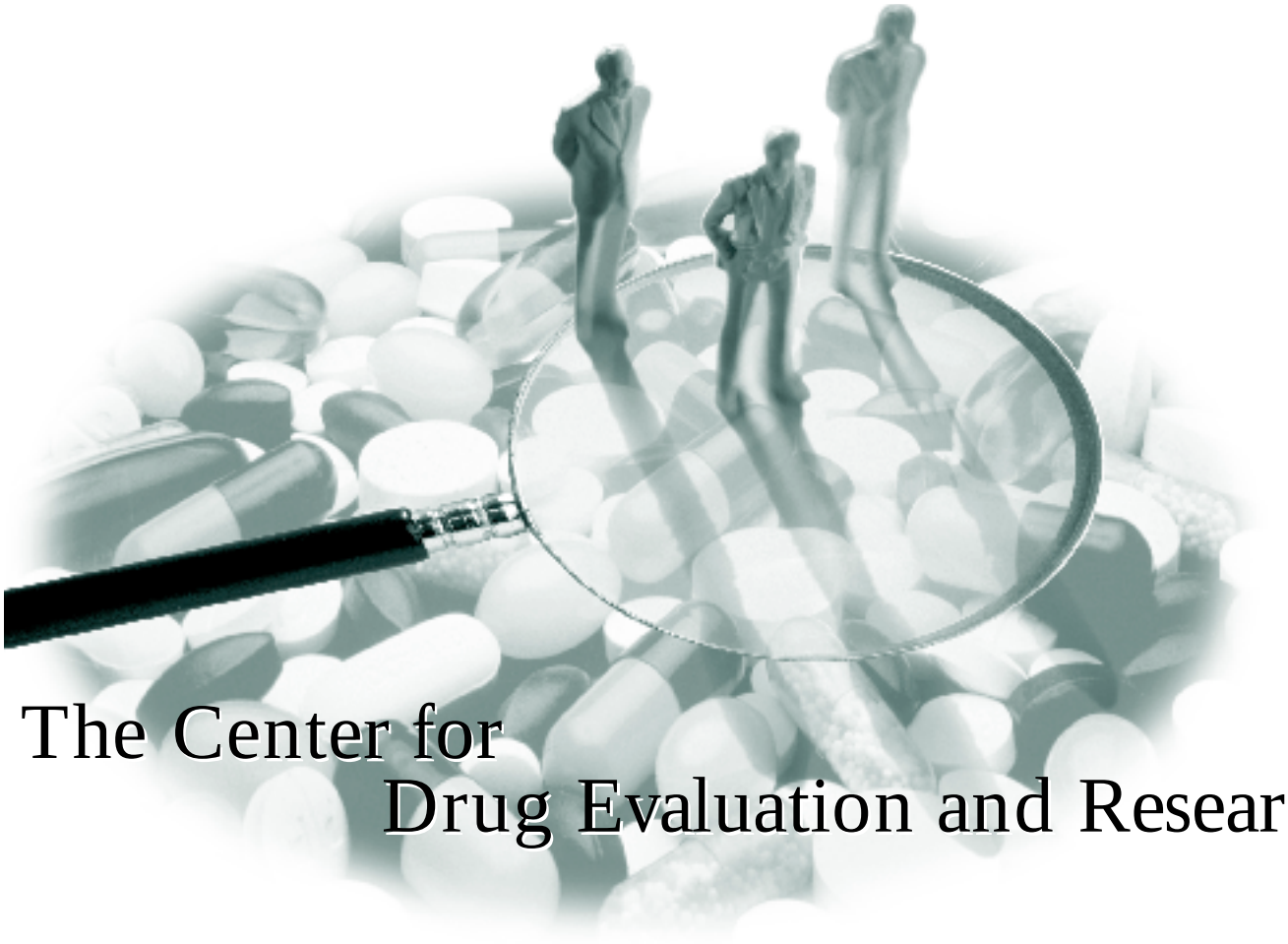

The Center for Drug Evaluation and Research:

Modern medicines are helping Americans live healthier, longer, and more productive lives. Many diseases that once took an early toll on lives and health are now cured or better managed with the help of medicine. American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world.

The main consumer watchdog in this system is the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). The center's best-known job is to evaluate new drugs before they can be sold (see "Benefit vs. Risk: How CDER Approves New Drugs," p. 33). The center's evaluation not only prevents quackery, but it also provides doctors and patients the information they need to use medicines wisely. The center makes sure that safe and effective drugs are available to improve the health of consumers. CDER ensures that prescription and over-the-counter (OTC) drugs, both brand name and generic, work correctly and that their health benefits outweigh their known risks.

The center is part of one of the nation's oldest consumer protection agencies (see "The Evolution of U.S. Drug Law," p. 37). CDER is the largest of FDA's five centers, with nearly 2,000 employees. Approximately half are physicians or scientists. Other centers have responsibility for medical and radiological devices, food, cosmetics, biologics, and veterinary drugs.

What Is a Drug?

Consumers usually think of drugs as the medicines they take to treat illnesses, but most Americans use CDER-regulated drug products every day to maintain health. Drugs include more than just medicines. For example, fluoride toothpastes, antiperspirants, dandruff shampoos, and sunscreens are all considered "drugs." Some medicines can be purchased in a store without a prescription, while others require a doctor's prescription.

Most drugs that CDER regulates are manufactured by a chemical process. Other products used to maintain health or to treat illness use a biological process in their manufacture, as do blood products. These products, known as biologics, are regulated by the Center for Biologics Evaluation and Research and must also be approved before they are sold. The most common examples of biologics are vaccines. Vitamins and dietary supplements can be sold without prior approval from FDA and are regulated by the Center for Food Safety.

Prescription Drugs

Prescription medicines must be administered under a doctor's supervision or require a doctor's authorization for purchase. There are several reasons that medicines are required to be sold by prescription. The disease or condition may be serious and

The Consumer Watchdog for Safe and Effective Drugs

require a doctor's management. The same symptoms can be caused by different diseases that only a doctor can diagnose. The different causes may require different medicines. Some medicines can be dangerous when used to treat the wrong disease.

Over-the-Counter (OTC) Drugs

OTC drug products are available to consumers without a doctor's prescription (see "A Special System for OTC Drugs," p. 36). Consumers can successfully diagnose many common ailments and treat them with readily available OTC products. These range from acne products to cold medications. As with prescription drugs, CDER closely regulates OTC drugs to ensure that they are safe, effective, and properly labeled. FDA has been evaluating the ingredients and labeling of OTC products that have been marketed for many years. In some cases, familiar brands or products have been withdrawn from the market because they were ineffective or unsafe.

There is a growing trend for Americans to participate more actively in their healthcare decisions. As this trend continues, many more medications purchased will be OTC drugs. Some drugs are approved for first-time sale as over-the-counter products. However, consumers have more choices today than ever because many drugs are switched from prescription to OTC status (see "Now Available Without a Prescription," p. 68).

With both old, familiar products and new, unfamiliar products sold over the counter, consumers can face bewildering choices. CDER has undertaken a major overhaul of the labels found on OTC medicines (see "New Drug Label Spells It Out Simply," p. 92). Thanks to improved labeling, consumers will soon be better able to make better informed choices about their OTC medicines and know when to seek professional advice.

Generic Drugs

A "generic" drug is a chemical clone of a drug sold under a brand name (see "FDA Ensures Equivalence of Generic Drugs," p. 61). There are generic versions of both prescription and over-the-counter medicines. For example, ibuprofen is the generic name of the anti-inflammatory drug sold under the brand names Motrin or Advil. The biggest difference between a generic drug and a brand name drug is usually price. A generic drug often costs about 30 percent less than the brand name drug. Widespread use of generics helps control medical costs and insurance premiums.

Drug Development and Review

Drug companies seeking to sell a drug in the United States must first test it. The company then sends CDER the evidence from these tests to prove the drug is safe and effective for its intended use. A team of CDER physicians, statisticians, chemists, pharmacologists and other scientists reviews the company's data and proposed labeling (see "The Review Team," p. 38). If this independent and unbiased review establishes that a drug's health benefits outweigh its known risks, the drug is approved for sale. The center doesn't actually test drugs itself; although, it does conduct limited research in the areas of drug quality, safety, and effectiveness standards.

Before a drug can be tested in people, the drug company or sponsor performs laboratory and animal tests to discover how the drug works and if it's likely to be safe and work well in humans (see "The Beginnings: Laboratory and Animal Studies," p. 14). Next, a series of tests in people is begun to determine if the drug is safe when used to treat a disease and if it provides a real health benefit (see "Testing Drugs in People," p. 18).

Reforming the U.S. Drug Review Process

Until this century, prescribing and taking drugs was a risky business for doctor and patient alike. Little was known about drugs, no scientific standards existed, and sometimes medicines caused illnesses rather than curing or preventing them. The U.S. drug review process assures that drugs are safe and effective. It had been lauded for years for the scientific and manufacturing quality it ensures in our drugs. However, for decades, the review process drew criticism for taking too long.

Getting beneficial drugs on the market quickly is just as much a part of CDER's public health mandate as keeping unproven and dangerous drugs off. Early in the 1990s,

CDER started reforming the drug review process to speed the delivery of new drugs to consumers while preserving high standards of quality and safety.

To obtain added resources for reform, the FDA, Congress, and the pharmaceutical industry negotiated the Prescription Drug User Fee Act of 1992. These added resources come from the drug company and are called user fees. As a result, the center has been able to hire more scientists to review marketing applications for drugs. As part of the deal, CDER agreed to phase in ambitious performance goals reviewing priority new drugs in six months or less and standard new drugs in a year or less (see "Review Priorities," p. 35). The center also standardized policies, improved communications, and streamlined many burdensome rules and regulations. CDER has created a review process that not only honors sound scientific principles, but also sound management principles as well.

The outcomes of the reform far exceeded expectations. Review times were cut in half even as the number of drugs approved in a year doubled. CDER's management reforms even improved programs that were not helped by user fees. Many of CDER's reforms were incorporated into the FDA Modernization Act and the reauthorization of the Prescription Drug User Fee Act, passed into law in 1997. As part of that law, CDER agreed to further ambitious goals for improved communications, more standardization, and even quicker reviews. In 1997, the Ford Foundation and the John F. Kennedy School of Government at Harvard University presented the FDA with the prestigious Innovations in American Government Award for its successful reforms.

FDA's MedWatch program enables healthcare professionals and consumers to report suspected problems with their drugs.

Helping Everyone Benefit from Drugs

While awards and kudos testify to CDER's successes, the center realizes that the drug development and review process doesn't serve all Americans as well as it could. In some cases, a lack of incentives was hindering the development of new drugs for people with rare disorders. In other cases, we don't know enough about how existing drugs work for children, women, and the elderly.

Congress passed the Orphan Drug Act to provide incentives to companies to research and develop medicines for people who have disorders that affect fewer than 200,000 Americans. The most powerful incentive in the law is marketing exclusivity. Once the FDA approves a company's product for a designated orphan disease, competitors are legally blocked from introducing an identical competing product for seven years. Other provisions provide grants, help from the FDA in designing research protocols that will meet regulatory requirements, and tax credits.

A series of bioethical reforms in the 1960s resulted in federal government rules that protect people who volunteer to take part in medical tests (see "Protecting Human Subjects," p. 24). These reforms sharply curtail the unnecessary risks faced by volunteers and prevent the exploitation of vulnerable groups, such as charity patients, prisoners or people in the military. An unintended side effect of these reforms, however, was to stunt the development of scientific knowledge about how drugs worked in children, minorities, women, and the elderly. The center has begun implementing a series of reforms to make sure that these groups are included in clinical trials and that knowledge about the effects of existing drugs in these groups is collected and developed (see "Pediatric Drug Studies: Protecting Pint-Sized Patients," p. 78, and "Medications and Older Adults," p. 82).

On the Watch for Drug Problems

Once a drug is approved for sale in the United States, CDER's consumer protection mission doesn't stop. It monitors the use of marketed drugs for unexpected health risks. If new, unanticipated risks are detected after approval, CDER takes action to inform the public, change a drug's label, or even remove a product from the market. In addition to evaluating regular reports from manufacturers, FDA's MedWatch program enables healthcare professionals and con-

sumers to report suspected problems with their drugs (see "MedWatch: FDA's 'Heads Up' on Medical Product Safety," p. 54).

CDER makes sure that an adequate supply of drugs will always be available. Sometimes, manufacturers run into production problems that might endanger the health of patients that depend on a drug (see "When a Drug Is in Short Supply," p. 64).

Protecting Drug Quality

The center also promotes public health by regulating the manufacture of drugs and setting standards for drug quality (see "An Inside Look at FDA On-Site," p. 47). CDER works closely with FDA's field inspectors to make sure that manufacturers comply with current good manufacturing practices. Before a drug is approved, investigators determine if the manufacturing data in the application are accurate. Once a drug is approved, another inspection is required to show the firm can consistently make a drug in large quantities. Periodic inspections check a firm's overall operation.

In addition to setting standards for safety and effectiveness, the center also sets standards for drug quality and manufacturing processes. The center is working closely with manufacturers to see where streamlining can cut red tape without compromising drug quality. As the pharmaceutical industry has become increasingly global, the center is involved in international negotiations with Japan and the European Union to harmonize standards for drug quality and data needed to approve a new drug. This harmonization will go a long way toward reducing the number of redundant tests manufacturers do and help ensure drug quality for consumers at home and abroad.

Drug Information and Advertising

Accurate and complete information is vital to the safe use of drugs. While drug companies have traditionally promoted their products directly to physicians, more and more, they are advertising directly to consumers (see "Direct to You: TV Drug Ads That Make Sense," p. 74). While advertising of over-the-counter drugs is regulated by the Federal Trade Commission, CDER oversees the advertising of prescription drugs. Advertisements for a drug must contain a truthful summary of information about its effectiveness, side effects, and circumstances when its use should be avoided.

In addition to its efforts to improve the information that accompanies over-the-counter drugs, CDER monitors a voluntary program that seeks to provide consumer information in the pharmacy for prescription drugs (see "A Dose of Clear Directions for Rx Drug Users," p. 88). The center watches this program closely to ensure that it meets its goals for quantity and quality of information.

Getting Consumer Input

Protecting consumers means listening to them as well. CDER routinely consults with the American people in making its decisions about the drugs they use. It holds public meetings about once a week to incorporate expert and consumer input into its decisions (see "Getting Outside Advice for Close Calls," p. 41). The center also announces many of its decisions in advance so that members of the public, academia, industry, trade associations, consumer groups, and professional societies can comment and make suggestions before decisions become final (See "How to Comment," p. 96). In addition, CDER is holding annual public meetings with consumer and patient groups, professional societies and pharmaceutical trade associations to obtain enhanced public input into its planning and priority-setting practices.

The center's present and future mission remains constant: to ensure that drug products available to the public are safe and effective. The center's yardstick for success will always be improving the consumer's health and well-being. CDER has additional resources for the pharmaceutical industry, healthcare professionals, and consumers (see "How to Obtain Information," p. 98).

CDER makes sure that an adequate supply of drugs will always be available.